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REMARKS

Claims 3-8, 33, and 36 remain in the application for further prosecution. Claim 33 has been amended to clarify the invention relative to the cited references.

Rejection Under 35 USC 103(a)

A new rejection has been made under 35 USC 103(a). Claims 3, 5, 6, 33 and 36 have been rejected as unpatentable (i.e. obvious) over Buechler (U.S. 6,133,855) in view of Hillman et al. (U.S. 4,756,884). The claims cover a microfluidic device and, as the Examiner points out, *"Apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function."* Previous arguments regarding Buechler have emphasized his teaching that, with his structure liquid is accelerated as it enters a wide region containing an array of posts. That is, the structure and its function are intertwined when the structure determines how liquid flows at a given rate through the device. Alternatively, the desired performance is not achieved unless the device is properly configured for the expected liquid flow.

The Examiner has pointed out the structural features Buechler's device has in common with that of the Applicants. However, he concedes that Buechler does not teach the use of a reagent deposited on an absorbent substrate. Therefore, Hillman was cited as supplying the use of reagent-containing substrate, arguing that locating the substrate where predictable results are achieved would be "obvious to try". The Applicants contend that, combining Hillman with Buechler is not obvious, but relies on hindsight in view of the invention as claimed.

The teachings of Hillman are ambiguous at best. Hillman does show a device in his Fig. 1A that could be similar to those of Buechler and the Applicants, in that a capillary passageway supplies a wider area containing reagents. In discussing Fig. 1A Hillman says the reagents are dried on the surface (column 18, lines 16-32). Hillman says nothing about

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structures in the wider region (20 in Fig. 1), so one must assume that liquid entering region 20 is free to fill the region as it will. It might trap air bubbles and thus not contact all of the reagents on the surface. But, if a reagent-containing substrate were to be added to region 20 it should be evident that obtaining uniform contact with the substrate would be more difficult, since the substrate presents an obstacle that could hinder the flow of liquid. Furthermore, if the reagent-containing substrate is fibrous in nature, capillary forces would be created and they would also affect the flow of liquid.

Buechler improves contact with reagents disposed on the surface of his wide region by locating the reagents on the surface of posts, which limit the space available for liquid flow and raise the effective capillarity and the liquid velocity. If successful, as Buechler teaches it is, there is no reason to place the reagent on a substrate and separate the substrate from the posts. Nor would it be obvious to space the posts so as to lower the effective capillarity and reduce the liquid velocity, thereby obtaining uniform contact with the substrate. In other words, why would one skilled in the art make such changes to the Buechler design?

If one wanted to place their reagents on a substrate, it would seem that one would follow Buechler's lead by wrapping the substrate around posts to achieve the alleged advantage of increased liquid velocity. It should follow that the substrate would be uniformly contacted and such a design might be expected to achieve good results. However, if the substrate is *not* wrapped around the posts, it could be placed in various locations, with and without posts. But, the results would not be predictable and testing would be required. In the absence of the present disclosure, one skilled in the art could not predict the results, that is, whether placing the reagent-containing substrate adjacent a set of posts disposed to both direct fluid flow and reduce the effective capillarity would provide good results. Not only would there be no motivation to do so,

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but such arrangements are no more than something to try.

The present microfluidic device is inherently more complex than the device at issue in the KSR case. In KSR, a single Jepson claim stated that it was an improvement to an adjustable accelerator pedal to place an electronic throttle connection on a fixed pivot. Since the advantage of avoiding movement of the throttle connection was considered obvious, the claim was determined to be invalid. Unfortunately, the court took the opportunity to expand the scope of obviousness, including the question of obvious to try. The court assumed where *"there are a finite number of identified, predictable solutions a person of ordinary skill in the art has a good reason to pursue the known options within his or her technical grasp"* (emphasis added). The court further relied on the "common sense" of one skilled in the art. However, these considerations may have applied to the KSR accelerator pedal, they lose their force when microfluidic technology is the subject.

An important question with respect to obvious to try is one of predictability. That is, if a group of possible solutions to a problem can be listed, it may not be evident that any of the potential solutions will be successful. The Applicant's problem was how to distribute a liquid sample uniformly over a reagent-containing substrate in an enclosed space, while expelling air. Trapping air would prevent achieving the desired uniform response of the reagent. Using an array of posts in a manner contrary to Buechler should not be considered obvious to try and could not be predicted to be successful without experimental evaluation.

With regard to Hillman, the Examiner notes that Hillman suggests that the reagents can be disposed on an absorbent substrate. Hillman does not go further and does not discuss how such reagent-containing substrates would be deployed. Furthermore, Hillman does not suggest using posts or other structures to assist in distributing liquid samples. The Examiner

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must jump to the conclusion that it would be obvious to add the substrate of Hillman to the Buechler device, but without any reason other than quoting from the KSR opinion.

Dependent claims 3-8 and 36 should be allowable if, as the Applicants contend, independent Claim 33 is patentable over Buechler in view of Hillman.

Claim 3 adds a second column of posts which, as the Examiner notes, is shown by Buechler. However, such a configuration is not relied on for patentability, rather it is a preferred embodiment.

Claim 5, 6, and 36 cover alternatives in which the location of the absorbent substrate is specified. As previously discussed, the location of an absorbent substrate is not obvious unless one considers "obvious to try" to render any and all location to be obvious. However, predictability is not available in the development of microfluidic devices.

Claim 4 was rejected under 35 USC 103(a) as unpatentable over Buechler and Hillman, in view of Peters. Again, the Examiner relied on KSR to support his rejection. While Claim 4 is only dependent from Claim 33 and should be patentable, it has been previously pointed out that Peters taught the use of posts with wedge-shaped cutout in a different manner than they are used in the Applicant's design. Peters empties capillaries with his cutouts, while in the Applicant's inventions the cutouts are positioned 90 degrees from the direction of liquid flow.

Claims 7 and 8 were rejected under 35 USC 103(a) as unpatentable over Buechler and Hillman in view of Columbus, who is cited for teaching ramp structures, again relying on KSR. Claims 7 and 8 are dependent from Claim 33 and also should be allowable. As has been pointed out previously, Columbus uses opposed set of grooves to spread liquid in all directions. The Applicants spread liquid across the entrance to the reagent-containing well, which is

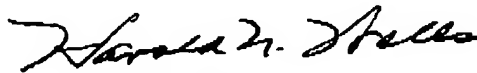
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structurally and functionally different.

In view of the amendments and the above remarks the Examiner is urged to allow the amended claims. If further amendments are believed necessary, the Examiner is invited to contact the Applicant's attorney at the telephone number provided below.

Respectfully submitted,



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